Complete Summary

GUIDELINE TITLE

Management of breast cancer in women. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of breast cancer in women. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2005 Dec. 50 p. (SIGN publication; no. 84). [214 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Scottish Intercollegiate Guidelines Network (SIGN). Breast cancer in women. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN), Scottish Cancer Therapy Network; 1998 Oct. 64 p. (SIGN publication; no. 29).

Any amendments to the guideline will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug for which important revised regulatory and/or warning information has been released.

On August 31, 2005, Genentech and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of updated cardiotoxicity information related to the use of Herceptin (trastuzumab), obtained from the National Surgical Adjuvant Breast and Bowel Project (NSABP) study (B-31), a randomized, Phase III trial that was conducted in 2043 women with operable, HER2 overexpressing breast cancer (IHC 3+ or FISH+). This study demonstrated a significant increase in cardiotoxicity in patients who were randomized to the Herceptin-containing arm as compared to patients who received chemotherapy alone. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Breast cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing
Obstetrics and Gynecology
Oncology
Radiation Oncology
Radiology
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based guidelines for the management of breast cancer in women

TARGET POPULATION

Women with breast cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis and Evaluation

1. Encouragement of breast awareness and self-examination
2. Referral from primary to specialist care
3. Assessment of breast abnormality through clinical examination, imaging, and sampling the lesion for cytological/histological assessment (fine needle aspirate cytology [FNAC] or core biopsy)
4. Magnetic resonance imaging (MRI)
5. Ultrasound
6. Mammography (Note: mammography is not recommended in women under the age of 35 years unless there is a strong suspicion of carcinomas)

Treatment/Management

1. Surgery
    - Breast conserving surgery
    - Mastectomy
    - Breast reconstruction
    - Axillary surgery
2. Management of ductal carcinoma in situ
    - Mastectomy
    - Breast conserving surgery (lumpectomy)
    - Irradiation following breast conserving surgery
3. Radiotherapy
    - Adjuvant radiotherapy, including chest wall and supraclavicular fossa radiotherapy
    - Axillary radiotherapy (considered but not recommended)
    - Internal mammary node chain radiotherapy (considered but not recommended)
4. Systemic therapy
    - Adjuvant chemotherapy
    - Neoadjuvant chemotherapy
    - Anthracycline and taxane therapy (epirubicin and taxanes)
    - Biological therapies (mono and adjuvant trastuzumab therapy)
    - Vinorelbine
    - Capecitabine
    - Bisphosphonates
    - Endocrine therapy (tamoxifen, ovarian ablation, aromatase inhibitors)
    - Management of menopausal symptoms with megestrol acetate and depot intramuscular medroxyprogesterone acetate
5. Psychological care
6. Follow up
7. Palliative care

MAJOR OUTCOMES CONSIDERED

- Recurrence of disease
- Survival rates

- Treatment morbidity
- Psychological morbidity

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature searches were initially conducted in Medline, Embase, Cinahl, and the Cochrane Library using the year range 1998–2002. The literature search was updated to cover the period up to December 2003. Key websites on the Internet were also used, such as the National Guidelines Clearinghouse. These searches were supplemented by the reference lists of relevant papers and group members' own files. The Medline version of the main search strategies can be found on the Scottish Intercollegiate Guidelines Network (SIGN) website.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g., case reports, case series)

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgment. The extent to which a study meets a particular criterion - e.g., an acceptable level of loss to follow up - and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by SIGN executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline

development record and ensure that the basis of the guideline development group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgment is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgment on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgment.

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, SIGN has introduced the concept of considered judgment.

Under the heading of considered judgment, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Directness of application to the target population for the guideline.
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them.)

- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgment. Once they have considered these issues, the group is asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 6 of the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

SIGN 29: Verbatim extract from the previous version of the guideline, SIGN 29, published in 1998. This material covers areas that were not updated in the current version of the guideline. It should be remembered that these older recommendations have not been developed with the rigour of current SIGN methodology and the evidence on which they are based may have been superseded. The grading system of these recommendations does not map consistently to the current SIGN grading system.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development.

Peer Review

All SIGN guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. A number of general practitioners (GPs) and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to a lay reviewer in order to obtain comments from the patient's perspective. The comments received from peer reviewers and others are carefully tabulated and discussed with the chairman and with the guideline development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the SIGN Editorial Group for that guideline to ensure that each point has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. Each member of the guideline development group is then asked formally to approve the final guideline for publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

The grades of recommendations (A-D; SIGN 29) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Diagnosis, Referral and Investigation

C - Women should be encouraged to become aware of the feel and shape of their breasts, so that they are familiar with what is normal for them. (SIGN 29)

C - Women should be encouraged to report any change from normal to their general practitioner. (SIGN 29)

Investigation of Symptomatic Breast Cancer

B - All patients should have a full clinical examination. (SIGN 29)

B - Where a localised abnormality is present, patients should have imaging usually followed by fine needle aspirate cytology or core biopsy. (SIGN 29)

B - A lesion considered malignant following clinical examination, imaging, or cytology alone should, where possible, have histopathological confirmation of malignancy before any definitive surgical procedure takes place (e.g., mastectomy or axillary clearance). (SIGN 29)

D - Patients should be seen at a one-stop, multidisciplinary clinic involving breast clinicians, radiologists, and cytology.

C - Clear lines of communication should be maintained between the primary care team and staff in the breast unit. (SIGN 29)

C - The general practitioner (GP) should be made aware of the information given to the patient and relatives. (SIGN 29)

A - Psychological support should be available to women diagnosed with breast cancer at the clinic.

C - Centres and units should develop an integrated network of cancer care using common clinical guidelines, management protocols, and strategies of care. (SIGN 29)

Imaging of Symptomatic Disease

B - In patients with symptomatic disease, two-view mammography should be performed as part of triple assessment (clinical assessment, imaging, and tissue sampling) in a designated breast clinic. (SIGN 29)

B - Mammography is not recommended in women under the age of 35 years unless there is a strong suspicion of carcinoma. (SIGN 29)

C - Magnetic resonance imaging (MRI) should be considered in specific clinical situations where other imaging modalities are not reliable, or have been inconclusive, and where there are indications that magnetic resonance imaging is useful.

Surgery

Conservative Surgery Versus Mastectomy

A - All women with early stage invasive breast cancer who are candidates for breast conserving surgery should be offered the choice of breast conserving surgery (excision of tumour with clear margins) or modified radical mastectomy.

A - The choice of surgery must be tailored to the individual patient, who should be fully informed of the options and who should be aware that breast irradiation is required following conservation and that further surgery may be required if the margins are positive.

C - Breast conserving surgery is contraindicated if:

- The ratio of the size of the tumour to the size of the breast would not result in acceptable cosmesis.
- There is multifocal disease or extensive malignant microcalcification on mammogram.
- There is a contraindication to local radiotherapy (e.g., previous radiotherapy at this site, connective tissue disease, severe heart and lung disease, pregnancy).

C - Central situation of the tumour is not a contraindication to conservation, although it may require excision of the nipple and areola, which may compromise cosmesis.

Breast Reconstruction after Mastectomy

C - The possibility of breast reconstruction should be discussed with all patients prior to mastectomy. (SIGN 29)

Surgical Management of the Axilla

A - Axillary surgery should be performed in all patients with invasive breast cancer.

Management of Ductal Carcinoma In Situ

Choice of Mastectomy or Breast Conserving Surgery

B - Women with ductal carcinoma in situ who are candidates for breast surgery should be offered the choice of lumpectomy or mastectomy.

Irradiation Following Breast Conserving Surgery

A - Women who have undergone breast conserving surgery should be offered postoperative breast irradiation.

Radiotherapy

Adjuvant Radiotherapy

A - Radiotherapy should be given following mastectomy or breast conserving surgery to reduce local recurrence where the benefit to the individual is likely to outweigh risks of radiation related morbidity.

Selecting the Appropriate Site

Chest Wall and Supraclavicular Fossa Radiotherapy

D - The supraclavicular field should be irradiated in all patients with four or more positive axillary nodes.

Systemic Therapy

Adjuvant Chemotherapy

A - All women under the age of 70 years, with early breast cancer should be considered for adjuvant chemotherapy.

C - Women with oestrogen receptor-positive tumours who receive chemotherapy should be considered for additional endocrine therapy, especially if they are under 35 years.

Neoadjuvant Chemotherapy

A - Neoadjuvant chemotherapy should be considered for women with large cancers as it improves the rate of breast conservation and is not detrimental to long term outcome.

Anthracycline and Taxane Therapy

Advanced Disease

Epirubicin

A - Anthracyclines should be prescribed in preference to non-anthracycline regimens in the adjuvant setting, as they offer additional benefits. Epirubicin may be preferred as it causes less cardiac adverse effects.

Taxanes

A - Taxanes should be considered in patients with advanced disease.

Biological Therapies

Trastuzumab Monotherapy

C - Trastuzumab should be reserved for those patients whose tumours have human epidermal growth factor receptor 2 (HER2) overexpression.

Trastuzumab Combination Therapy

A - Combination therapy of trastuzumab with a taxane is recommended in women with metastatic breast cancer.

Vinorelbine and Capecitabine Therapy

Capecitabine

A - Either capecitabine or vinorelbine should be considered for patients with advanced breast cancer.

Role of Bisphosphonates

Bisphosphonates and Metastatic Disease

A - Bisphosphonates should be routinely used in combination with other systemic therapy in patients with metastatic breast cancer with symptomatic bone metastases. The choice of agent for an individual patient depends on individual circumstances.

Endocrine Therapy

Premenopausal Women

A - Premenopausal women whose tumours are not shown to have absent oestrogen or progesterone receptors should be considered for adjuvant endocrine therapy.

A - In premenopausal women with advanced disease, the combination of tamoxifen plus ovarian ablation should be offered before tamoxifen therapy alone.

Postmenopausal Women

<u>Advanced Disease</u>

A - In postmenopausal women with breast cancer tamoxifen remains the treatment of choice as initial therapy in the adjuvant setting. If there are relative contraindications to its use (high risk of thromboembolism or endometrial abnormalities) or intolerance, an aromatase inhibitor can be used in its place.

A - Postmenopausal patients should be considered for a switch to an aromatase inhibitor after either two to three years or after five years of tamoxifen therapy.

A - In postmenopausal women with advanced disease, third generation aromatase inhibitors should be considered before either tamoxifen or megestrol acetate.

Timing of Surgery and Chemotherapy

C - All treatments for patients with early breast cancer should be started as soon as is practical. Young women with oestrogen receptor negative tumours may benefit particularly from early initiation of chemotherapy following surgery.

Management of Menopausal Symptoms

B - Megestrol acetate or depot intramuscular medroxyprogesterone acetate may be considered to control the severity of hot flushes in women with breast cancer.

Psychological Care

The Role of the Breast Care Nurse

C - All women with a potential or known diagnosis of breast cancer should have access to a breast care nurse specialist for information and support at every stage of diagnosis and treatment.

Education

D - Breast care nurse specialists should have appropriate education and experience.

Identifying Distress

B - The measurement of the presence of psychological symptoms in women with breast cancer should be tailored to the individual circumstances of the patient (e.g., presence of high level of distress or risk factors for problems).

B - Routinely administered questionnaires are not recommended for the detection of clinically significant psychological symptoms in women with breast cancer who do not have specific risk factors for severe anxiety or distress.

Psychological Support for Women with Breast Cancer and Their Families

Group Based Psychological Interventions

A - Group psychological interventions should be available to women with breast cancer who feel it would suit their needs.

A - Supportive expressive therapy is recommended for patients with advanced cancer and cognitive behavioural therapy for patients with localised, locoregional, or advanced disease.

Individual Interventions

A - Cognitive behavioural therapy (in group or individual format according to preference and availability) should be offered to selected patients with anxiety and depressive disorders.

A - Computer and telephone-based interventions should not routinely be offered to patients.

Communication Methods

A - Women with breast cancer should be offered audiotapes or follow up summary letters of important consultations.

A - Clinical encounters with women with breast cancer should facilitate patient choice about treatment decisions (assuming patients wish to participate in the decision making process).

A - Written agendas, prompt sheets, and decisions aids should be used to improve communication with women with breast cancer.

A - Clinicians should be encouraged to attend validated training in communication skills.

Follow-up

Improving Outcomes

Patients without Recurrence

Detection of Recurrence in the Treated Breast and New Primary in the Contralateral Breast

C - Mammography should be used to detect recurrence in patients who have undergone previous treatment for breast cancer.

Identifying Patients with Metastatic Disease

Detection of Distant Metastases

B - Routine diagnostic tests to screen for distant metastases in asymptomatic women should not be performed.

Specialist Palliative Care

B - Patients with breast cancer should have access to input from a specialist palliative care team.

Definitions

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

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A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

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Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

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Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g. case reports, case series)

4: Expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Optimal screening for and management of breast cancer can increase the overall and disease-free survival rate and reduce the risk of disease recurrence
- Improved quality of life

POTENTIAL HARMS

Side effects and complications of chemotherapy, radiotherapy, and surgery

CONTRAINDICATIONS

CONTRAINDICATIONS

Breast conserving surgery is contraindicated if:

- The ratio of the size of the tumour to the size of the breast would not result in acceptable cosmesis.
- There is multifocal disease or extensive malignant microcalcification on mammogram.
- There is a contraindication to local radiotherapy (e.g., previous radiotherapy at this site, connective tissue disease, severe heart and lung disease, pregnancy).

Relative contraindications to tamoxifen include high risk of thromboembolism or endometrial abnormalities.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Board and is an essential part of clinical governance. It is acknowledged that every Board cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Key points for audit are identified in the original guideline document.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of breast cancer in women. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2005 Dec. 50 p. (SIGN publication; no. 84). [214 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Oct (revised 2005 Dec)

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Government (Non-U.S.); Scottish Office Department of Health

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Dr Douglas Adamson (Chair) Consultant Clinical Oncologist, Ninewells Hospital, Dundee; Dr David Cameron, Senior Lecturer in Medical Oncology, Western General Hospital, Edinburgh; Ms Kathy Clarke, National Cancer Audit Coordinator, Scottish Cancer Therapy Network, Edinburgh; Ms Sue Cruickshank, Lecturer in Cancer Nursing, Napier University, Edinburgh; Ms Lorraine Dallas, National Manager, Breast Cancer Care, Glasgow; Dr John Donald, Referrals Adviser, Lothian Primary Care Trust, Edinburgh; Dr Jane Edgecombe, Consultant in Palliative Medicine, Beatson Oncology Centre, Glasgow; Ms Carla Forte, Principal Pharmacist, Beatson Oncology Centre, Glasgow; Professor Neva Haites, Professor of Medical Genetics, University of Aberdeen; Dr Adrian Harnett, Consultant in Clinical Oncology and Radiology, Norfolk and Norwich University Hospital; Dr Paul Keeley, Consultant in Palliative Medicine, Glasgow Royal Infirmary; Ms Gillian Little, Macmillan Specialist Nurse, Ninewells Hospital, Dundee; Dr Elizabeth Mallon, Consultant Pathologist, Western Infirmary, Glasgow; Mr Michael McKirdy, Consultant Breast Surgeon, Royal Alexandra Hospital,

Paisley; Dr Moray Nairn, Programme Manager, SIGN; Dr Russell Pickard, Consultant Radiologist, West of Scotland Breast Screening Programme, Glasgow; Mr Duncan Service, Senior Information Officer, SIGN; Dr James Tuckerman, General Practitioner, Buckie; Mr Patrick Walsh, Consultant Surgeon, Raigmore Hospital, Inverness; Dr Craig White, Macmillan Consultant in Psychosocial Oncology, Ayrshire Central Hospital

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of interests were made by all members of the guideline development group. Further details are available from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Scottish Intercollegiate Guidelines Network (SIGN). Breast cancer in women. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN), Scottish Cancer Therapy Network; 1998 Oct. 64 p. (SIGN publication; no. 29).

Any amendments to the guideline will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: management of breast cancer in women. Scottish Intercollegiate Guidelines Network, 2005 Dec. 2 p. Available electronically from the Available electronically from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Electronic copies available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from SIGN Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 28, 1999. The information was verified by the guideline developer as of August 19, 1999. This NGC summary was updated by ECRI on March 3, 2006. The updated information was verified by the guideline developer on April 6, 2006.

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DISCLAIMER

NGC DISCLAIMER

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